REMARKS UNDER 37 CFR § 1.111

Formal Matters

Claims 123-130 are pending after entry of the amendments set forth herein.

Claims 123-130 were examined and rejected. No claims were allowed.

Claims 127 is amended to more distinctly claim the invention. Support for the amendment is found in the previously pending, now canceled claims and throughout the specification, particularly at page 5, lines 19-24.

No new matter has been added by the new claims. Accordingly, their entry by the Examiner is respectfully requested.

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

Rejection under 35 U.S.C. §101

Claim 127 is rejected 35 U.S.C. §101, on the grounds that the claim is directed to non-statutory subject matter. This rejection is respectfully traversed.

Applicants respectfully submit that the claim of Claim 127, as amended, is directed to statutory subject matter.

In view of foregoing, the Examiner is respectfully requested to withdraw the rejection of claim 127 under 35 U.S.C. §101.

Rejection under 35 U.S.C. §112, first paragraph

Claims 123-130 are rejected under 35 U.S.C. §112, first paragraph, for reasons of record. The Applicants respectfully traverse this rejection.

The Office is respectfully referred to the arguments presented in the response filed in this case on September 27, 2002, which are reiterated herein.

In particular, the language of the Office Action again indicates that the Office is impermissibly reading a limitation into the claims (i.e., that the claims are directed to full-length

cDNAs), and then focusing upon whether the specification describes a cDNA having an open reading frame. Applicants submit that this is not proper.

Specifically, the Office Action states that "the applicants have failed to provide reasons for description of the claimed genus of polynucleotides **in view of the lack of description of a full length sequence of the cDNA** from which SEQ ID NO:972 was derived" (emphasis added) as a grounds for the rejection.

Applicants are not aware of any interpretation of the law of written description that requires that the specification identify a "full length sequence of the cDNA" Even the "Synopsis of Application of Written Description Guidelines" (hereafter "Synopsis"; posted on the USPTO world wide website on March 1, 2000) does not support this assertion. The Synopsis states that "For example, a cDNA's principle attribute would include its coding region." (emphasis added)[1] Applicants again note that the claims are not so limited to cDNAs. Furthermore, the Synopsis is not stating that a coding region is the only attribute of a polynucleotide, but rather is an example of attributes, since these "include" a coding region.

As noted above, the claims are not so limited to cDNAs, but rather are *directed to* a genus of polynucleotides, all of which share the feature of "at least 150 contiguous nucleotides of SEQ ID NO:972". As previously argued, and as Dr. Somerville has opined, the instant specification has adequately described a vast variety of polynucleotides, for example probes, vectors, clones, restriction fragments and PCR products that contain at least 150 nucleotides of SEQ ID NO:972. The full length cDNA is merely one of many species encompassed within the claimed genus. It is not recited or referred to in any way by the claims, and there is no basis in fact or law for viewing that species as an essential or critical element.

The Office Action cites no basis in the law (nor are the applicants aware of any basis) for the proposition that a genus which is described in the specification nevertheless fails to meet the written description requirement because one single species is not disclosed. In fact, *In re Angstadt*[2] states that applicants' specification need not describe every possible species within a broadly claimed genus in order to satisfy the requirement of 35 U.S.C §112, first paragraph. As stated by the court in *In re Alton*, "If a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if

[1] Synopsis of Application of Written Description Guidelines, page 31.
[2] 537 F.2d 498, 502-503 (CCPA 1976)

every nuance of the claims is not explicitly described in the specification, then the adequate written description requirement is met."[3]

In the field of recombinant DNA technology, making and using specific nucleic acid sequences routinely involves incorporating the sequences into larger molecules, including cloning and expression vectors and PCR products. Moreover, these specific nucleic acid sequences retain at least one utility, e.g., as probes for diagnosing cancers. The variety of useful larger molecules comprising a specific nucleic acid sequence is almost limitless. In this field, the practical reality is that larger nucleic acid molecules into which an inventive nucleic acid sequence can be inserted should be viewed as the functional milieu in which an inventive sequence can be made and used. In this context, inventors of nucleic acids would be deprived of meaningful patent protection if they were limited to claims directed to only the specific nucleic acid.

Again, the Office concludes that since the specification does not describe the sequence of the full-length sequence of a cDNA comprising SEQ ID NO:972, and the claims encompass such a sequence, the specification does not provide an adequate written description of the claimed invention. However, this is only a particular species of the genus of the claimed polynucleotides. The lack of written description of a single species is not sufficient to support a rejection of the claimed genus.

In view of foregoing, the Examiner is respectfully requested to withdraw the rejection without further discussion.

[3] *In re Alton*, 76 F.3d 1168, 1177 (Fed. Cir. 1996).

Conclusion

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number 2300-1487.

Respectfully submitted,
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